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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/321,655	05/28/1999	STANTON L. GERSON	640100-304	6848

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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
03/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/321,655	GERSON, STANTON L.	
	Examiner	Art Unit	
	QUANG NGUYEN, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Interference No. 105,197 has been terminated by a decision favorable to applicant. *Ex parte* prosecution is resumed.

Amended claims 2-5 are pending in the present application, and they are examined on the merits herein.

Claim Objections

Claim 4 is objected to because of the phrase "the transduced human progenitor cells". This is because in claim 5 from which claim 4 is dependent on, only transformed human hematopoietic progenitor cells are recited and not transduced human progenitor cells. To be consistent, the transformed human progenitor cells should be recited in claim 4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Reese et al. (Proc. Natl. Acad. Sci. 93:14088-14093, 1996; Cited previously) as evidenced by

Prockop, D.J. (Science 276:71-74; Cited previously). ***This is a new ground of rejection.***

Reese et al. already disclosed retroviral transduction of a mutant methylguanine DNA methyltransferase gene into human CD34 cells (hematopoietic progenitor cells as defined by the specification on line 29, page 4) which are resistant to a combination of O^6-benzylguanine and 1,3-bis(2-chloroethyl)-1-nitrosourea (Abstract). The transduction was carried out in CD34 cells cocultured on a human bone marrow stroma generated by culturing passaged and irradiated bone marrow mononuclear cells in myeloid long-term culture medium (column 2, first paragraph, page 14089). It is apparent that the bone marrow human stroma contains passaged, irradiated and adhered bone marrow mononuclear cells, and this cell population encompasses isolated mesenchymal stem cells or isolated multipotential bone marrow stromal cells (MSCs) as evidenced by the teachings of Prockop (see at least the abstract; and particularly page 72, col. 3), including the disclosure that the adherent cells used as feeder layers for hematopoietic stem cells have many of the characteristics of MSCs isolated by their adherence to plastic in the absence of non-adherent cells.

Reese et al. did not disclose whether human bone marrow mononuclear cells were derived from the same adult patients from whom CD34 cells were obtained. Therefore, the used human bone marrow stromal cells are allogeneic to the hematopoietic progenitor cells. Furthermore, Reese et al. disclosed that the transduced CD34 cells were removed from the bone marrow stromal layer containing irradiated and

passaged stromal cells with a cell dissociation buffer (last sentence, first paragraph, column 2, page 14089).

Accordingly, the method taught by Reese et al meets every limitation of the claims as broadly written. Therefore, the reference anticipates the instant claims.

Claims 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Nolta et al. (Blood 86:101-110, 1995, Cited previously) as evidenced by Prockop, D.J. (Science 276:71-74; Cited previously). ***This is a new ground of rejection.***

Nolta et al. disclosed a transduction method for human CD34 cells isolated from bone marrow and peripheral blood with retroviral vectors containing either the bacterial neo gene, or normal human glucocerebrosidase in the presence of a stroma generated by human allogeneic bone marrow stromal cells which were irradiated and passaged prior to the plating of CD34 cells (Abstract, and column 1, page 102). The utilized bone marrow stromal cell population derived from bone marrow spicules is devoid of most hematopoietic cells (column 1, third paragraph, page 102), and it contains isolated mesenchymal stem cells or isolated multipotential bone marrow stromal cells (MSCs) as evidenced by the teachings of Prockop (see at least the abstract; and particularly page 72, col. 3), including the disclosure that the adherent cells used as feeder layers for hematopoietic stem cells have many of the characteristics of MSCs isolated by their adherence to plastic in the absence of non-adherent cells. Nolta et al. further disclosed the isolation of transduced, nonadherent CD34 cells after the transduction by vigorous

flushing and plating the collected cells twice to eliminate adherent stromal cells (column 1, last paragraph, page 102).

Accordingly, the method taught by Nolta et al meets every limitation of the claims as broadly written. Therefore, the reference anticipates the instant claims.

Claims 2 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Wells et al. (Gene therapy 2:512-520, 1995) as evidenced by Prockop, D.J. (Science 276:71-74; Cited previously). ***This is a new ground of rejection.***

Wells et al. disclosed a transduction method for human bone marrow CD34 progenitor cells from a Gaucher patient with a retroviral vectors containing a normal human glucocerebrosidase cDNA, in the presence of an autologous bone marrow stromal support containing passaged and irradiated adherent stromal cells depleted of hematopoietic cells and macrophages (see at least Abstract and Materials and Methods, particularly pages 518-519). The utilized bone marrow stromal support contains isolated mesenchymal stem cells or isolated multipotential bone marrow stromal cells (MSCs) as evidenced by the teachings of Prockop (see at least the abstract; and particularly page 72, col. 3), including the disclosure that the adherent cells used as feeder layers for hematopoietic stem cells have many of the characteristics of MSCs isolated by their adherence to plastic in the absence of non-adherent cells. Wells et al. further disclosed the isolation of transduced, nonadherent CD34 cells after the transduction (column 1, first full paragraph, page 519).

Accordingly, the method taught by Wells et al meets every limitation of the claims as broadly written. Therefore, the reference anticipates the instant claims.

Response to Arguments

Applicant's arguments related to the above rejections in the Amendment filed on 9/20/00 (page 3) have been fully considered but they are respectfully not found persuasive.

Applicant argues basically that neither Reese nor Nolta disclose the co-culturing of human hematopoietic progenitor cells with isolated human mesenchymal stem cells and transducing the human hematopoietic stem cells with exogenous genetic material in the presence of the isolated human mesenchymal stem cells.

Please note that the passaged, irradiated human bone marrow stromal cell population used in any of the references cited above contains isolated mesenchymal stem cells or isolated multipotential bone marrow stromal cells (MSCs) as evidenced by the teachings of Prockop (see at least the abstract; and particularly page 72, col. 3), including the disclosure that **the adherent cells used as feeder layers for hematopoietic stem cells have many of the characteristics of MSCs isolated by their adherence to plastic in the absence of non-adherent cells**. It is further noted that the human bone marrow stromal cell population is also depleted of hematopoietic cells and macrophages.

Accordingly, the teachings of Reese et al., Nolta et al. or Wells et al. meet every limitation of the claims as written for the reasons set forth above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/QUANG NGUYEN, Ph.D./
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